

Notice of Allowability

Application No.

09/580,797

Applicant(s)

IWEN ET AL.

Examiner

Art Unit

Jeanine A Goldberg

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/9/03; 10/17/03; 10/20/03.
2. ☒ The allowed claim(s) is/are 2-5 and 20-27.
3. ☒ The drawings filed on 30 May 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>1003</u> . |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____ | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |


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SUPERVISOR, PATENT EXAMINER
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DETAILED ACTION

1. This action is in response to the papers filed October 9, 2003, October 17, 2003 and October 20, 2001. Currently, claims 2-5, 20-27 are pending.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

3. Authorization for this examiner's amendment was given in a telephone interview with Tong Li on October 21, 2003.

The application has been amended as follows:

25. (currently amended) A kit as claimed in claim 24, ~~wherein said amplified sequence is detected via incorporation of a detectable label~~further comprising a detectable label for detecting said amplified sequence.

26. (currently amended) A kit as claimed in claim 24, ~~wherein said amplified sequence is detected by gel electrophoresis of said amplified sample~~further comprising a gel apparatus for performing gel electrophoresis of said amplified sequence.

27. (currently amended) A kit as claimed in claim 24, ~~wherein said amplified sequence is compared to a sequence selected from the group consisting of SEQ ID NOs: 3-23, thereby identifying said pathogenic fungus it present~~further comprising nucleic acids having sequences of SEQ ID NOs: 3-8.

REASONS FOR ALLOWANCE

4. The following is an examiner's statement of reasons for allowance.

The claims are drawn to amplifying *Aspergillus* species using primers consisting of SEQ ID NO: 1 and 2 (Claims 2-5, 20-21). Applicant has filed a Declaration which illustrates the unexpected results of SEQ ID NO: 1 and 2 over the prior art. The first Declaration submitted provided a comparison between ITS1 and ITS4 which was not deemed to be the closest prior art. However, SEQ ID NO: 1 and 2 appear to be more sensitive and amplify all of the *Aspergillus* species as compared with the ITS1 and ITS4 primers of White (Declaration filed January 21, 2003). In the declaration filed by Peter Iwen, on July 28, 2003, a comparison between ITS5 and ITS4 which is deemed by the examiner to be the closest prior art. The comparison between the ITS5 and ITS4 primers and the instant primers of SEQ ID NO: 1 and 2 demonstrates the unexpected results of SEQ ID NO: 1 and 2 as a primer pair (see Exhibit A and B). The ITS5/ITS4 primer set of White was found to be incapable of amplifying *A. fumigatus* and *A. terreus* under the same conditions (page 5 of Declaration filed July 28, 2003). Thus, it is clear that ITS5 and ITS4 are not functionally equivalent to SEQ ID NO: 1 and 2 of the instant application.

Claim 22 is drawn to contacting nucleic acids with probes comprising SEQ ID NO: 3-8. The prior art does not teach sequences of SEQ ID NO: 3-8. Thus, Claim 22 is allowable.

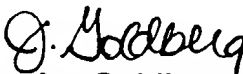
Upon the invitation of the examiner, applicants reintroduced Claims 23-27 directed to the primer pair of SEQ ID NO: 1 and 2. For the reasons above, the primer pair consisting of SEQ ID NO: 1 and 2 is allowable over the prior art.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 6:00 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jeanine Goldberg
Patent Examiner
October 21, 2003